

### **III. REMARKS/ARGUMENTS**

#### **A. Status of the Application**

Claims 1, 5, 8, 10-22 and 36 are pending. Claims 2-4, 6-7 and 9 have been cancelled. Claims 23-35 have been cancelled without prejudice or disclaimer as being drawn to a nonelected invention. Claims 1, 11 and 15-16 have been amended and claim 36 has been added in accordance with 37 C.F.R. §1.121(c)(1). It is respectfully submitted that claims 1, 11 and 15-16, as amended, and new claim 36 are supported by the specification as filed and are in condition for allowance or at least in better form for consideration on appeal. Further, claims 1, 11, 15-16 as amended and new claim 36 do not raise any new issues which require further search or substantial consideration on the part of the Examiner. For these reasons, it is requested that this amendment be entered under the provisions of 37 C.F.R. §1.116 as it places the application in condition for allowance or at least in better condition for appeal. Favorable consideration and allowance of claims 1, 5, 8, 10-22 and 36 in view of the foregoing amendments and the following remarks are respectfully requested.

#### **B. Finality of Office Action**

It is respectfully submitted that the finality of the Office Action mailed December 31, 2007 is premature and improper for the following reasons.

Section 706.07(a) of the MPEP states that:

“[S]econd or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).”

According to the Office Action, the claim amendments set forth in the Response filed on September 27, 2007:

“[N]arrowed the scope of the claims in such a way that required the Examiner to interpret each of bush plum, green tea extract and grape skin extract to an extent not required by the previous claims. This is because the previous claims comprised one of bush plum, green tea extract, grape skin extract or a mixture

thereof, whereas the newly amended claims comprise all three components”.  
(Office Action, page 2).

The Examiner’s attention is respectfully directed to original claim 6 which included a mixture of bush plum, green tea extract and grape skin extract and original claim 11 which required a combination of green tea extract, grape skin extract and bush plum. Thus, contrary to the Examiner’s comments, at least two of the original claims comprised all three of bush plum, green tea extract and grape skin extract.

Accordingly, it is respectfully submitted that the amendment of claims 1 and 15 did not necessitate the new ground of rejection made in the Office Action mailed December 31, 2007. Therefore, it is respectfully submitted that the finality of the Office Action mailed December 31, 2007 is premature and improper and it is respectfully requested that it be withdrawn.

**C. Rejection Under 35 U.S.C. § 112**

Claims 1, 5, 8 and 10-22 stand rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claims 1 and 15 have been amended to specify what is being claimed with respect to the terms “bush plum”, “green tea extract” and “grape skin extract.” Accordingly, it is respectfully requested that the rejection of claims 1, 5, 8 and 10-22 under 35 U.S.C. §112, second paragraph, be withdrawn.

**D. Rejection under 35 USC § 103(a) over Howard ‘277**

Claims 1, 5, 8 and 10-22 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,642,277 to Howard et al. (“Howard ‘277”). Insofar as it may be applied to the present claims, this rejection is respectfully traversed.

Independent claim 1 is directed to an antioxidant composition that includes a flavonoid and a mixture of at least two forms of vitamin E as primary ingredients and bush plum pulp and skin, green tea extract and grape skin extract as secondary ingredients. The primary ingredients are present in the composition in an amount of 30% to 85% by weight and the secondary

ingredients are present in the composition in an amount of 15% to 70% by weight. Also, the flavonoid and the mixture of vitamin E forms are present in the composition in a weight ratio of from 40/60 to 90/10 percent. According to claim 1 the flavonoid is selected from the group consisting of a flavone, a flavonol, an isoflavone, an isoflavonol, an analogue thereof, a pharmaceutically acceptable salt thereof, and a mixture thereof. Also according to claim 1, the at least two forms of vitamin E are selected from the group consisting of alpha, beta, delta, epsilon, gamma, zeta, eta, xi1, xi2, and sigma tocopherols, and alpha, beta, delta and gamma tocotrienols, and derivatives thereof. Further, according to claim 1, the bush plum pulp and skin comprises 5% vitamin C, the green tea extract comprises 35-95% polyphenols, and the grape skin extract comprises 30-82% polyphenols.

Each of claims 5, 8, 10-14, 18-20 depends, directly or indirectly, from and therefore includes at least the same elements as claim 1.

Independent claim 15 is directed to an antioxidant composition that includes:

- quercetin;
- a mixture of alpha, beta, delta, and gamma tocopherols;
- grape skin extract comprising 30-82% polyphenols;
- green tea extract comprising 35-95% polyphenols; and
- bush plum pulp and skin comprising 5% vitamin C.

According to claim 15, the quercetin and the mixture of tocopherols account for between 30% and 85% by weight of the antioxidant composition. Also according to claim 15, the quercetin and mixture of tocopherols are present in the composition in a weight ratio of from 40/60 to 90/10 percent.

Each of claims 16-17 and 21-22 depends, directly or indirectly, from and therefore includes at least the same elements as claim 15.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements is **not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art**. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a

**reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." Id. at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

In the present application, a prima facie case of obviousness does not exist for claims 1, 5, 8 and 10-22 in view of Howard '277 for the reasons set forth below.

**1. The Examiner has not shown that all words in the claim have been considered**

MPEP § 2143.03 states that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." Quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). However, in the present matter, the Examiner has not shown that all words in the claim have been considered. For example, claims 1 and 15 recite antioxidant compositions that include bush plum pulp and skin comprising 5% vitamin C and green tea extract comprising 35-95% polyphenols.

Howard '277 discloses a plant-derived flavonol-containing dry composition wherein at least 25% of the plant-derived material in the composition comprises polyphenols (Abstract). The dry composition is prepared from plant material selected from the group consisting of wine or grape juice (Col. 5, lines 41-49). Howard '277 further discloses that the compositions may comprise further components, such as those typically used in the food industry, such as nutrients, antioxidants, therapeutic substances, flavorings and sweeteners (Col. 9, lines 34-42). Howard '277, however, does not disclose or suggest bush plum pulp and skin comprising 5% vitamin C.

Howard '277 also discloses in Example 3 (Col. 13 line 1 to Col. 17, line 42) a series of volunteer studies using wine polyphenols to determine the antioxidant activity of red and white wine and polyphenol preparations in healthy volunteers. As noted at Col. 13, lines 46-51, green

tea extract was one of the test substances. The conclusions from the volunteer studies are set forth at Col. 17, lines 34-42 wherein it is noted that green tea extract was inactive.

Consequently, it is submitted that in the present case the Examiner has not factually supported a prima facie case of obviousness for claims 1 and 15 for the following reasons. Specifically, the Examiner has not shown how the prior art of record teaches or suggests an antioxidant composition that includes bush plum pulp and skin comprising 5% vitamin C or green tea extract comprising 35-95% polyphenols.

Howard '277 is silent as to bush plum pulp and skin and teaches away from including green tea extract in an antioxidant composition. Consequently, the disclosure in Howard '277 relied upon by the Examiner, does not obviate the antioxidant compositions of claims 1 and 15 or the claims that depend therefrom.

**2. The Examiner has not shown how the elements being combined produce a predictable result**

In the present case, the Examiner has not expressed any reason why the plant-derived flavonol-containing dry composition prepared from wine or grape juice disclosed by Howard '277 and green tea extract comprising 35-95% polyphenols would be combined in the same way as the antioxidant compositions of claims 1 and 15 to present a predictable result.

For the foregoing reasons, the examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claims 1 and 15 under 35 U.S.C. §103(a) over Howard '277 should be withdrawn.

Dependent claims 5, 8, 10-14, 18-20 depend from and further limit independent claim 1 and dependent claims 16-17 and 21-22 depend from and further limit independent claim 15, and therefore are deemed to be patentable over the prior art for the same reasons as noted above with respect to claims 1 and 15, respectively.

**E. Rejection under 35 USC § 103(a) over Fleischner '533**

Claims 1, 5, 8 and 10-22 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,291,533 to Fleischner ("Fleischner '533"). Insofar as it may be applied to the present claims, this rejection is respectfully traversed.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

In the present application, a prima facie case of obviousness does not exist for claims 1, 5, 8 and 10-22 in view of Fleischner '533 for the reasons set forth below.

**1. The Examiner has not shown that all words in the claim have been considered**

MPEP § 2143.03 states that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." Quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). However, in the present matter, the Examiner has not shown that all words in the claim have been considered. For example, claims 1 and 15 recite antioxidant compositions that include bush plum pulp and skin comprising 5% vitamin C, green tea extract comprising 35-95% polyphenols and grape skin extract comprising 30-82% polyphenols.

Contrary to claim 1, Fleischner '533 does not teach, suggest or motivate an antioxidant composition that includes a flavonoid and a mixture of at least two forms of vitamin E as primary ingredients and bush plum pulp and skin comprising 5% vitamin C, green tea extract comprising 35-95% polyphenols, and grape skin extract comprising 30-82% polyphenols as secondary ingredients in which the primary ingredients are present in the composition in an

amount of 30% to 85% by weight and the secondary ingredients are present in the composition in an amount of 15% to 70% by weight, and in which the flavonoid and the mixture of vitamin E forms are present in the composition in a weight ratio of from 40/60 to 90/10 percent, as claimed in claim 1.

Also, contrary to claim 15, Fleischner '533 does not teach, suggest or motivate an antioxidant composition that includes quercetin, a mixture of alpha, beta, delta, and gamma tocopherols, grape skin extract comprising 30-82% polyphenols, green tea extract comprising 35-95% polyphenols, and bush plum pulp and skin comprising 5% vitamin C, wherein the quercetin and the mixture of tocopherols account for between 30% and 85% by weight of the antioxidant composition, and wherein the quercetin and mixture of tocopherols are present in the composition in a weight ratio of from 40/60 to 90/10 percent.

Instead, Fleischner '533 discloses various dietary supplement compositions that are said to be designed to be responsive to specific blood types and to be "useful in achieving and maintenance of a healthy status". (Fleischner '533, Abstract and Column 2, lines 33-40). Fleischner '533 discloses a dietary supplement composition that is alleged to be designed for humans with Type A blood which includes 50-500 mg. of Vitamin C, 25-400 IU of Vitamin E (as d-alpha-tocopheryl succinate and 50% from natural d-alpha-, d-beta-, d-gamma-, and d-delta-tocopherols), 100-400 mcg. of folate, 10-50 mcg. of Vitamin B-12, 25-200 mg. of Hawthorn berry standardized extract, 50-250 mg. of quercetin dihydrate, 50-200 mg. of milk thistle seed extract, 10-50 mg. of alfalfa leaf, 10-50 mg. of Aloe vera leaf gel 200:1 concentrate, 10-100 mg. of Burdock root, 10-50 mg. of Fenugreek seed, 10-100 mg. of ginger root, 50-200 mg. of green tea leaf extract, 25-300 mg. of St. John's Wort standardized extract, 10-50 mg. of slippery elm bark, 10-50 mg. of skull cap root, 10-50 mg. of parsley leaf, 10-100 mg. of dandelion root, 10-50 mg. of chamomile flower, 10-50 mg. of sarsaparilla root, and 25-100 mg. of pueraria root extract. (Fleischner '533, Column 7 line 53 to Column 8 line 37). Using a conversion factor based on the purest form of Vitamin E in terms of International Units or "IU", 25-400 IU of Vitamin E is equal to 16.75-268 mg. of Vitamin E. Accordingly, while the dietary supplement composition disclosed by Fleischner '533 that is designed for humans with Type A blood includes green tea leaf extract, it does not include either one of bush plum or grape skin extract.

Thus, contrary to the antioxidant compositions of claims 1 and 15 of the present application, the dietary supplement composition disclosed by Fleischner '533 does not include bush plum pulp and skin comprising 5% vitamin C, green tea extract comprising 35-95% polyphenols and grape skin extract comprising 30-82% polyphenols.

Consequently, it is submitted that in the present case the Examiner has not factually supported a prima facie case of obviousness for claims 1 and 15 for the following reasons. Specifically, the Examiner has not shown how the prior art of record teaches or suggests an antioxidant composition that includes bush plum pulp and skin comprising 5% vitamin C, green tea extract comprising 35-95% polyphenols and grape skin extract comprising 30-82% polyphenols.

For the foregoing reasons, the examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claims 1 and 15 under 35 U.S.C. §103(a) over Fleischner '533 should be withdrawn.

Dependent claims 5, 8, 10-14, 18-20 depend from and further limit independent claim 1 and dependent claims 16-17 and 21-22 depend from and further limit independent claim 15, and therefore are deemed to be patentable over the prior art for the same reasons as noted above with respect to claims 1 and 15, respectively.

**F. New Claim 36**

New claim 36 is directed to an antioxidant composition that includes quercetin, a mixture of alpha, beta, delta, and gamma tocopherols, grape skin extract comprising 30-82% polyphenols, green tea extract comprising 35-95% polyphenols, bush plum pulp and skin comprising 5% vitamin C, and a carrier comprising gum acacia, xanthan gum, gum tragacanth, gum ghatti, and aloe vera gel extract. According to new claim 36:

- the quercetin and the mixture of tocopherols are primary ingredients and the primary ingredients are present in the composition in an amount of from 30% to 85% by weight;



- the bush plum pulp and skin, green tea extract, and grape skin extract are secondary ingredients and the secondary ingredients are present in the composition in an amount of from 15% to 70% by weight;
- the quercetin and the mixture of tocopherols are present in the composition in a weight ratio of from 40/60 to 90/10 percent; and
- the quercetin, the mixture of tocopherols, the grape skin extract, the green tea extract, and the bush plum pulp and skin are present in the composition in a weight ratio of 1:2 to 2:1, with respect to the carrier.

Similar to the discussion noted above with respect to claims 1 and 15, it is respectfully submitted that new claim 36 is patentable over Howard '277, Fleischner '533 and all other references of record.

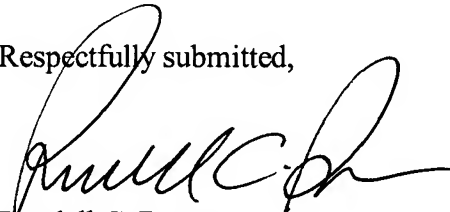
### **Conclusion**

It is believed that all matters set forth in the Office Action have been addressed. Favorable consideration and allowance of claims 1, 5, 8, 10-22 and 36 are respectfully requested. Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration of the claims, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

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Respectfully submitted,

  
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